Covance Clinical Research Unit Inc.

Covance Clinical Research Unit Inc.
309 West Washington Avenue, Suite Four East
Madison, WI 53703

Covance TES Informed consent

Volunteer Information and Consent Form

Study Sponsor:	Philip Morris U.S.A.
Covance Study Doctor:	Russell M. Dixon, M.D.
Study Title:	A Multi-Center Study to Determine the Exposure of Adult U.S. Smokers to Cigarette Smoke
Study No.:	PM Project No. 1137

Invitation

You are invited to be in a research study at Covance. This study will collect information about smoking or non-smoking habits and attitudes, as well as samples of blood and urine, from adult smokers and adult non-smokers. This study is also being conducted at other research sites around the country.

The Purpose of This Study

We are doing this study to see if there are differences in certain substances found in body fluids, such as blood and urine, between adult smokers and adult non-smokers. We are also trying to learn about habits and attitudes between adult smokers and adult non-smokers.

Covance Clinical Research Unit Inc. is paid to conduct research. The study doctors in this study work for Covance, but do not have a financial interest in the outcome of this study.

Who Can Be in This Study

Volunteers for this study must meet certain requirements. The study staff will ask you questions about your current and past health, what kinds of medicines you take and what kinds of operations or diseases you may have had or have.

About 5,000 adult smokers and 1,000 non-smokers will participate in this study. At this site, the study doctor will choose up to 500 people to be in this study. Some of the volunteers must already be smokers, and others must already be non-smokers. Non-smokers or former smokers will NOT be asked to smoke. Smokers who decide to quit smoking during the study may do so and remain in the study unless other reasons call for their removal. This study does not offer smoking cessation treatment for people who decide to quit smoking, or any other health benefits.

To be in this study, you must be 21 years of age or older. Females may not be pregnant. Use of certain products or medications may or may not be allowed in this study. Please read the following chart carefully.

MAY I HAVE...?	YES	NO	FOR HOW LONG?
SMOKERS:			
• Any tobacco product other than manufactured cigarettes (pipe, cigar, snuff, chewing tobacco, bidis, or roll-your-own cigarettes		X	3 months before, and during the study
• Nicotine containing products (nicotine patch, nicotine spray, nicotine inhaler, nicotine gum, nicotine lozenge, nicotine pill or, nicotine-containing water)		X	3 months before, and during the study
NON-SMOKERS:			
• Any tobacco product before the study (manufactured cigarettes, pipe, cigar, snuff, chewing tobacco, bidis, or roll-your-own cigarettes)		X	5 years before the study, and during
• Nicotine containing products (nicotine patch, nicotine spray, nicotine inhaler, nicotine gum, nicotine lozenge, nicotine pill or, nicotine-containing water)		X	5 years before, and during the study
ALL VOLUNTEERS:			
• Caffeine Products	X		No restrictions to usual amount
• Alcohol Products	X		No restrictions to usual amount
• Prescription Medicines	X		No restrictions to usual amount
• Over-the-Counter Medicines (Non-prescription, including herbal products)	X		No restrictions to usual amount
• Donate(d) or receive(d) blood products		X	3 months before, and during the study
• Participate(d) in research study study		X	3 months before, unless approved by the doctor

What Will Happen in This Study?

Before you can be in this study, you must read and sign this consent form. If you qualify to be in the study after that, your participation in this study will last over a period of up to 5 days. In this study you will:

- Come to the research unit twice, five days apart, for an outpatient visit. Each outpatient visit will last about __ hours.

We are also interested in contacting you one year after this study is completed. We may have another research study you might be interested in, and we would tell you this when we contact you in a year from now. You are asked to give us permission to contact you on the last page of this consent form. You do not have to agree to be contacted in one year in order to participate in this study.

IN THIS STUDY, YOU WILL:

- Have vital signs recorded (blood pressure, heart rate, respiration and temperature)–*twice*
- Review your medical history, your smoking history, and what medicines you take–*twice*
- Fast (no food) for 6 hours-*once*
- Have your blood drawn for laboratory tests-*once*
- Collect your urine over a 24-hour period and turn in-*once*
- Be tested for pregnancy (females)-*twice*
- Have a lung function test-*once*
- Complete a questionnaire-*once*
- Use a topography instrument over a 24-hour period and turn in (SMOKERS ONLY)-*once*
- Collect used cigarette butts/filters over a 24-hour period and turn in (SMOKERS only)-*once*
- Have your picture taken for study identification

OTHER PROCEDURES AND RESTRICTIONS

Laboratory Test Results

If you have significantly abnormal laboratory test results needing medical follow-up, you will be notified by mail, and asked to contact the research unit with your physician's name and phone/fax number. The laboratory results will be forwarded to your physician in order that

s/he may give you medical advice as appropriate. The laboratory results will not be given to you directly.

Urine Collection
Once during this study, you must collect all your urine over a 24-hour period and keep it in a cooler until you bring it to the research unit. You will be provided with collection containers and a storage cooler.

Lung Function Test
Once in this study, you will perform a lung function test - a painless breathing test of your lung capacity.

Questionnaire
Once during this study, you will complete a questionnaire that will ask for personal information about your lifestyle history and habits.

Topography Instrument
SMOKERS: Once during this study, you must use a topography instrument with all the cigarettes you smoke over a 24-hour period. This instrument will record information about your smoking habits. The study staff will show you how to use it. You may not keep the topography instrument, and must return it to the research unit.

Cigarette Butt/Filter Collection
SMOKERS: Once during this study, you must collect and turn in all cigarette butts/filters from the cigarettes that you smoked over a 24-hour period.

ABOUT BLOOD SAMPLES
During this study, about ___ blood samples will be taken from a vein in your arm.

The total amount of blood being drawn in this study is about ____cups. For comparison, you give about 2 cups of blood at one time when you donate a unit at a blood collection center.

Risks of Being in This Study

The risks of having blood drawn include bruising, infection, bleeding, and blood clot formation. Sometimes having blood drawn can sting and be uncomfortable. Some people faint when they have their blood drawn.

Treatment for Injuries

Your safety is the major concern of every member of the staff. Please contact the study staff as soon as possible if you have injuries. The phone number for Covance is (608) 283-6060.

Covance will provide immediate medical treatment and follow-up care for injuries caused by being in this study. The costs for any other medical problems not caused by being in this study are your responsibility.

If You Have Questions

Please contact the study doctor or the study staff with any questions you may have. They can be reached at (608) 283-6060.

For questions about your rights as a research volunteer, please contact the Institutional Review Board (IRB) office (608) 283-4069. The Covance CRU IRB is the review board that approved this study. Letters may be sent to the attention of the IRB at 309 W. Washington Avenue, Suite 4E, Madison, WI 53703.

Benefits of Being in This Study

This study will not improve your health or treat any medical problem you may have. If you have medical problems, you should see your own doctor about your care.

Payment for Your Time

You will not be paid for the first visit to the research unit. If you complete all required study activities after the first visit, you will receive $300. SMOKERS: If you fail to return the topography instrument to the research unit, you will not be paid at all. A check will be mailed to you at the end of the study after you have completed all required study activities.

After you begin the study, if you are released, or choose to stop you will only be paid for the time you spent in the study (at a lesser rate).

No taxes are deducted from your check. You are responsible for paying any state, federal, or Social Security taxes.

If you receive more than $600 in one calendar year from Covance, you will receive a 1099 tax form the following January. Covance reports the money paid to you to the Internal Revenue Service.

Costs to You

There are no costs to volunteers. The study sponsor pays all the study costs.

Protecting Your Privacy

As much as possible, your name and identity will be kept private. You will be identified by a unique number on many study records.

The people who are allowed to look at your study records include staff from Covance Clinical Research Unit Inc, Covance Laboratories Inc., and possibly governmental agencies as required by law. People from these organizations will be allowed to see and copy your study records. The study records will be checked to see that the study was conducted properly.

This study may be written about in medical or scientific journals, but your name will never be used in any public reports on this study.

The sponsor, Philip Morris USA, will only see the study data and results without your name on it. No identifying information will be given or shown to sponsor in any written, electronic or other form.

Stopping the Study Early

The study sponsor and/or the study doctor can stop the study at any time. You may also be required to stop being in the study if you do not follow the study directions, or do not meet the study requirements.

Leaving the Study

Your decision to be in this study is completely voluntary. You may leave the study at any time. There are no penalties for leaving the study early. You will not lose any benefits for which you qualify. You will be told about any new information about the study that might make you change your mind about being in this study.

Volunteering to be in This Study

You may take as much time as you need to think about being in this study. Before you sign this form, please ask any questions you have about your part in this study or about the research. The staff will try to answer fully and clearly any questions you may have before, during and after this study. **You do not lose any of your legal rights by signing this form.** You will receive a signed copy of the Volunteer Information and Consent Form. You do not have to agree to be contacted in one year in order to remain in this study.

Please read the following paragraphs out loud to the person obtaining the consent.

I have read the information in this study consent form. I have asked the staff any questions I have had at this time about my part in this study and about this research. I volunteer to take part in this study of my own free will.

Print Your Full Name _____ Date of Birth _____

Street Address _____ Social Security Number _____

City _____ State _____ Zip Code _____

Telephone Nos. (Home) _____ (Work) _____

Your Signature _____ Date/Time _____

I have received a copy of this study consent form.

Your Signature _____ Date _____

I give my permission to be contacted in one year: YES_____ NO_____

Your Signature _____ Date _____

**********DO NOT WRITE BELOW THIS LINE**********

Signature of Person Obtaining Consent and Verification of Literacy _____ Date/Scientific Time _____

Drivers Lic. # or other ID _____ I.D. Verified by _____